

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

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OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT:

Review of a California SLN(Section 24c) for the Use of Hydrogen

Peroxide and Peroxyacetic Acid on Cucurbits

TO:

Product Manager Team 33

Regulatory Management Branch I Antimicrobials Division(7510C)

FROM:

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01/19/01

THRU:

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I.D. NO .:

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DP BARCODE:

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SUBMISSION:

S584904

CASE NO .:

069457

PC CODE:

063201 Peroxyacetic Acid

MRID NOS .:

None

Introduction:

The California Department of Pesticide Regulation(CDPR) submitted an application for a Special Local Need Registration(SLN) for the use of a product identified as Tsunami 100 for use on curcurbits grown for seed only (Note: Block 1. on the SLN application lists Novartis Seeds, Inc. as the applicant for registration). However the label included in the SLN package is for an Ecolab product identified as Oxy-15. The Regulatory Management Branch(RMB) I(conversation with M. Terry) advised RASSB that Novartis is a distributor for Ecolab for this product. The active ingredients on the SLN application and on the label are peroxyacetic acid and hydrogen peroxide. The product registration number cited on the SLN application is EPA Reg. No. 1677-164-2A and on the CDPR submission containing use directions is 1677-164. The SLN application states in Block 5 that this is a non food/non feed use per Section 12832 of the California Food & Agricultural Code.

Background:

RASSB understands that the proposed SLN registration for the proposed seed treatment use has already been issued. The SLN application was received by EPA on 8/8/2000 and was received in RASSB on 11/27/2000.

There are a large number of uses for the active ingredients, hydrogen peroxide and peroxyacetic acid, both under FDA 21 CFR and EPA 40 CFR Titles. Under the 40 CFR 180.1196 and 180.1197 there are uses for both chemicals on food commodities and on food contact surfaces.

Conclusions:

- Under the conditions of use proposed on the SLN submission for Tsunami 100, RASSB considers that the proposed use is a non-food use.
- 2. There is no likelihood of residues of either hydrogen peroxide or peroxyacetic acid occuring in cucurbit plants grown from treated seed.
- 3. Consequently, there is no reasonable expectation of secondary residues occurring in meat, milk poultry or eggs from the proposed use(40 CFR 180.6(a)(3).

Recommendations:

RASSB has no objection to the issuance of the SLN registration for the proposed use of this Tsunami 100 formulation as a seed treatment to cucurbit seeds.

Detailed Considerations

OPPTS GLN 860.1100 Chemical Identity

The name of the product is Tsunami 100. The product contains 15.0% peroxyacetic acid and

11.0% hydrogen peroxide.

The active ingredients in the formulation are:

Component(CAS No.)	Empirical Formula	Structural Formula	Formula Weight
Hydrogen Peroxide(7722-84-1)	H_2O_2	н-О-О-Н	34
Peroxyacetic Acid(79-21-0)	$C_2H_4O_3$	Н ₃ -С-С-О-ОН О	75

OPPTS GLN 860.1200 Proposed Use

The CDPR submission proposes use of the Tsunami 100 product as a seed treatment for use on cucurbits (grown for seed) to control bacterial fruit blotch and gummy stem blight.

The product is to be mixed with water to produce a solution containing 1600 ppm of peroxyacetic acid. (Note: The solution would also contain 1173 ppm of hydrogen peroxide.)

Seeds should be submerged in the treatment solution for 30 minutes. Seeds should then be drained and dried.

One application is to be made to the seed. Treated seed is not to be distributed to growers for commercial crop production for food use. Seed is to be utilized by the seed company, Novartis Seeds, for research trials.

OPPTS GLN 860.1500 Residue Chemistry

The residue chemistry guidelines offer guidance for food use/nonfood use determination under OPPTS GLN 860.1000(e)(2)(ii) for seed treatments. This includes cases where seed is treated either by the seed company(and dyed according to 40 CFR 153.155) or by the farmer(planter box or hopper treatments). In order for a seed treatment to be considered to be a nonfood use, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop.(Note: the HED Chem SAC issued guidance on the required level of quantitation to make a determination of no uptake of residues into the aerial portion of the plant grown from treated seed as being 5 ppb.). If residues occur in the aerial portion of the plant or if there are no data to make this determination, seed treatments are considered to be food uses requiring tolerances. However, if crops are grown for seed only, these crops may qualify for as nonfood uses provided there is no likelihood of residues in crops grown from the harvested seeds and the seeds or other parts of the treated crop are not diverted to food/feed use. Factors affecting this include the level of residues on the harvested seed, the half-life of seed residues and the weight of the seed in relation to that of the subsequent crop.

For the proposed SLN Registration, treatment is to be made with a formulation containing

peroxyacetic acid and hydrogen peroxide. Both of these chemicals are easily degraded by heat, sunlight, traces of heavy metals either in the ionic or finely divided state, ferments, enzymes or many kinds of dust and dirt.

Consequently, RASSB would expect residues on seed treated with the Tsunami 100 formulation to be rapidly degraded. No residues of peroxyacetic acid or hydrogen peroxide would be expected to occur in the plant grown from the treated seed or in the seed of that plant.

Degradation products would be expected to be acetic acid and water from peroxyacetic acid and to be water and oxygen from hydrogen peroxide.

RASSB concludes that the proposed use is a nonfood use. RASSB consultation with Dr. Rick Loranger, Senior Scientist in the Health Effects Division, confirmed this opinion.